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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/975,253 | 10/12/2001 | Paul A. Moore | PF196P1 | 8837 |

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 09/975,253 | Applicant(s) MOORE ET AL. | |
| | Examiner Sandra Wegert | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,16-24,26 and 37-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,16-24,26 and 37-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of Application, Amendments, and/or Claims

The Amendment, submitted 1 April 2005 has been entered. Claims 1-8, 16, 23, 24 and 26 are amended. Claims 9-15, 25 and 27-36 are cancelled. Claims 37-52 are new.

Claims 1-8, 16-24, 26 and 37-52 are under examination in the Instant Application.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

Withdrawn Objections And/or Rejections

35 USC § 112, first paragraph-Deposit Rules

The rejection of Claims 10-15 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement is *withdrawn*. Applicants canceled Claims 10-15 (1 April 2005).

Claim Rejections- 35 USC § 102

The rejection of Claim 25 for being anticipated by Hall, L. (1993, Accession. No. SSIL2R) is *withdrawn*. Applicants canceled claim 25 (1 April 2005).

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The rejection of Claims 25 and 26 under 35 U.S.C. 112, second paragraph, for being indefinite, is *withdrawn*.

Art Unit: 1647

Claim 25 was considered indefinite because of the phrase “stringent conditions,” (see previous Office Action, page 10, 2 November 2004). Applicants cancelled Claim 25 (1 April 2005). Claim 26 was considered indefinite for encompassing production of a polypeptide from a complementary nucleic acid- (referring to Claim 1(o)). Applicants cancelled subject matter in the independent claim referring to complementary nucleic acids (1 April 2004).

Maintained Objections and/or Rejections

35 U.S.C. § 101/112, first paragraph- Scope of Enablement.

Claims 1-8, 16-24, 26 and 37-52 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for the nucleic acids of SEQ ID NO: 1, degenerate variants encoding the polypeptide of SEQ ID NO: 2, vectors and isolated host cells comprising same, does not enable polynucleotides encoding variants or fragments of SEQ ID NO: 2. This rejection was previously made over Claims 1-9 and 16-26 (pages 3-5, 2 November 2004). Applicants cancelled Claims 9-15 and 25.

The claims are directed to the polynucleotides encoding SEQ ID NO: 2, polynucleotides encoding contiguous fragments of SEQ ID NO: 2, vectors and cells comprising the polynucleotides, and methods of recombinantly producing SEQ ID NO: 2. Claims 1-8, 16-24, 26 and 37-52 also encompass polynucleotides encoding polypeptides that are 20-50 contiguous residues, as well as compositions.

Applicants seem to argue that the short fragments of SEQ ID NO: 1 need not have activity to be enabled (Response, page 6, 1 April 2005) by the instant Specification. Applicant's

Art Unit: 1647

arguments have been fully considered but are not found to be persuasive for the following reasons:

The instant Application does not reasonably provide enablement for various fragments of the encoding polynucleotide, since the Specification discloses only use of SEQ ID NO: 1. This is because the proposed fragments are claimed using open (i.e., "comprising") language. Peptide fragments that are indefinite as to location on SEQ ID NO: 2 and indefinite as to structure and function, cannot be claimed using open language. Furthermore, there are no examples in the Disclosure of what polypeptides fall within the range of those that would be functionally useful as fragments. Amending claims to recite "an isolated polynucleotide consisting of an antigenic fragment of SEQ ID NO: 2," and then specifying location and length, for example would be remedial.

35 USC § 112, first paragraph – Written Description.

Claims 1-8, 16-24, 26 and 37-52 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicants seem to argue that the Written Description rejection is based on the examiner "impermissibly reading a functional limitation into the claims" (page 7, 1 April 2005).

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons:

Art Unit: 1647

The essence of Written Description of a genus of chemical compounds is "possession" of the claimed species, or, alternatively, possession of a significant number of claimed compounds such that the genus is well-represented. However, as discussed in the previous office action (page 5, 2 November 2004) there is a lack of guidance in the Specification and the prior art as to exactly what structure is required for the derivatives encompassed by Claims 1-8, 16-24, 26 and 37-52. The specification teaches the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2. However, the specification does not teach any *variants* of the polypeptide of SEQ ID NO: 2. Thus, the claims are drawn to a genus of molecules that are undefined. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus *as it is recited in the claims*. Additionally, the description of one polynucleotide species and one polypeptide species is not adequate written description of an entire genus of functionally equivalent compounds.

As explained in the previous Office Action (2 November 2004, page 6) conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making a polypeptide variant. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. *The nucleic acid itself is required*. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicants have not made and tested variants of SEQ ID NO: 2, or made and tested a representative number of species of the claimed genus.

Art Unit: 1647

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire Later than **SIX MONTHS** from the mailing date of this final action.

Advisory information

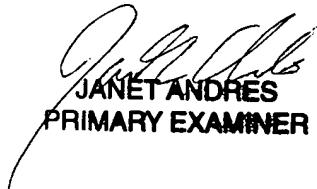
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
21 June 2005


JANET ANDRES
PRIMARY EXAMINER